

K062891

510(k) SUMMARY

**Indiana University Cyclotron Facility's
Proton Therapy System**

DEC 14 2006

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Indiana University Cyclotron Facility
2401 Milo B. Sampson Lane
Bloomington, Indiana 47408

Phone: (812) 855-2881
Facsimile: (812) 855-6645

Contact Person: Paul E. Sokol, IUCF Director

Date Prepared: September 26, 2006

Name of Device and Name/Address of Sponsor

Proton Therapy System (PTS)

Indiana University Cyclotron Facility
2401 Milo B. Sampson Lane
Bloomington, Indiana 47408-1398

Common or Usual Name

Proton Beam Therapy System (PBTS)

Classification Name

Medical Charged-Particle Radiation Therapy System

Predicate Devices

The Indiana University Cyclotron Facility PTS is substantially equivalent to the Loma Linda Medical Center Proton Beam Therapy System (K872369) and Ion Beam Applications, SA's, Proton Therapy Systems (K983024, K060695).

Intended Use / Indications for Use

The IUCF PTS is intended to deliver proton radiation treatment to patients with solid tumors or other diseases susceptible to radiation.

K062891

Technological Characteristics

IUCF's PTS is a charged particle radiation therapy system. The PTS contains three major systems: the Cyclotron System (CYS), JUSTIS, and the Treatment Systems (TS). The TS is divided into seven subsystems to carry out the proton treatment process: the Treatment Room Control System (TRCS); the Kicker Enable System (KES); the Beam Delivery System (BDS); the Dose Delivery System (DDS); the Patient Positioning System (PPS); the MPRI Radiation Interlock System (MIRS); and the Emergency Stop System (ESS). These subsystems work together to generate the desired dose level and distribution at the target site. Treatment System 2 (TS2) of the PTS, the subject of this 510(k) notice, employs a rotating gantry, which allows the proton radiation beam to be delivered to the target site from any direction in a plane. The gantry includes the gantry structure; retractable gantry floor; Digital Radiography panel positioning systems; gantry safety mechanisms; and gantry rotation controls. Computer control of the gantry is provided by the PPS.

Performance Data

Extensive performance testing conducted at the system and subsystem (hardware and software) levels, and electromagnetic compatibility, electromagnetic interference ("EMC/EMI") and electrical safety demonstrated that the system and subsystems met or exceeded design specifications, clinical performance requirements and EMC/EMI and electrical safety applicable standards. In all instances, the IUCF PTS functioned as intended.

Substantial Equivalence

The IUCF PTS is as safe and effective as the Loma Linda Medical Center Proton Beam Therapy System (K872369) and Ion Beam Applications, SA's, Proton Therapy Systems (K983024, K060695). The IUCF PTS has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the IUCF PTS and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that the IUCF PTS is as safe and effective as the predicate devices listed above. Thus, the IUCF PTS is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Indiana University Cyclotron Facility
c/o Jonathan S. Kahan
Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, N.W.
WASHINGTON DC 20004

DEC 14 2006

Re: K062891

Trade/Device Name: Proton Therapy System

Regulation Number: 21 CFR §892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: II

Product Code: LHN

Dated: December 1, 2006

Received: December 4, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K062891

Device Name: Proton Therapy System

Indications for Use:

Indiana University Cyclotron Facility's Proton Therapy System is a medical device intended to deliver proton radiation treatment to patients with solid tumors or other diseases susceptible to radiation.

Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K062891

Page ____ of ____